

**UNITED STATES INTERNATIONAL TRADE COMMISSION**  
**Washington, D.C.**

**In the Matter of**

**CERTAIN SILDENAFIL OR ANY  
PHARMACEUTICALLY ACCEPTABLE  
SALT THEREOF, SUCH AS SILDENAFIL  
CITRATE, AND PRODUCTS  
CONTAINING SAME**

**Inv. No. 337-TA-489**

**GENERAL EXCLUSION ORDER**

The Commission has determined that there is a violation of section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) in the unlawful importation and sale of certain sildenafil, or any pharmaceutically acceptable salt thereof, such as sildenafil citrate, and products containing same that infringe one or more of claims 1-5 of U.S. Patent No. 5,250,534 (“the ‘534 patent”).

Having reviewed the record in this investigation, including the recommended determination of the presiding administrative law judge and the written submissions of the parties, the Commission has made its determination on the issues of remedy, the public interest, and bonding. The Commission has determined that the appropriate form of relief is a general exclusion order issued under section 337(d)(2) prohibiting the unlicensed importation of sildenafil, or any pharmaceutically acceptable salt thereof, such a sildenafil citrate, and products containing same covered by one or more of claims 1-5 of the ‘534 patent.

The Commission has also determined that the public interest factors enumerated in 19 U.S.C. § 1337(d) do not preclude issuance of the general exclusion order, and that the bond during the

Presidential review period shall be in the amount of 100 percent of the entered value of the products subject to this order.

Accordingly, the Commission hereby **ORDERS THAT:**

1. Sildenafil, or any pharmaceutically acceptable salt thereof, such as sildenafil citrate, and products containing same covered by one or more of claims 1-5 of U.S. Patent No. 5,250,534 are excluded from entry for consumption into the United States, entry for consumption from a foreign trade zone, or withdrawal from warehouse for consumption, for the remaining term of the patent, except under license of the patent owner or as provided by law.

2. Sildenafil, or any pharmaceutically acceptable salt thereof, such as sildenafil citrate, and products containing same that are excluded by paragraph 1 of this Order are entitled to entry for consumption into the United States, entry for consumption from a foreign trade zone, or withdrawal from warehouse for consumption, under bond in the amount of 100 percent of entered value pursuant to subsection (j) of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(j), from the day after this Order is received by the President until such time as the President notifies the Commission that he approves or disapproves this action but, in any event, not later than sixty (60) days after the date of receipt of this action.

3. In accordance with 19 U.S.C. § 1337(l), the provisions of this Order shall not apply to products otherwise covered by this Order that are imported by and for the use of the United States, or imported for, and to be used for, the United States with the authorization or consent of the Government.

4. The Commission may modify this Order in accordance with the procedures described in section 210.76 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.76.

5. The Secretary shall serve copies of this Order upon each party of record in this investigation and upon the Department of Health and Human Services, the Department of Justice, the Federal Trade Commission, and the Bureau of Customs and Border Protection.

6. Notice of this Order shall be published in the *Federal Register*.

By Order of the Commission.

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Marilyn R. Abbott  
Secretary

Issued: